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Page 8**REMARKS/ARGUMENTS**The Specification Has Been Amended

Applicants have amended the specification to correct an obvious typographical error in the paragraph that bridges pages 40-41. In the last sentence of this paragraph at line 7 of page 41, the indefinite article "a" has been replaced with --an--. Following the amendment, this sentence recites "an increased content . . . ." This amendment of the specification is purely formal in nature. No new matter has been added to the specification by way of this amendment.

Status of the Claims

Claims 1-3 have been canceled.

Claims 5, 10, 11, 21, and 30 have been amended.

Claims 5, 21, and 30 have been amended to delete part (d). Also, part (c) of these claims has been amended to recite that the nucleotide sequence comprises at least 95% sequence identity to the sequence set forth in SEQ ID NO: 1 activity. Support for this amendment of part (c) of claims 5, 21, and 30 can be found in original claims 5, 21, and 30 and throughout the specification, particularly on page 14 at lines 1-6.

Claim 5 has been further amended to point out more distinctly that the method involves introducing a nucleotide construct into at least one cell of a plant. Support for this amendment of claim 5 can be found in original claim 5 and in the specification, particularly on page 11 at lines 10-14.

Claim 5 has been further amended to point out more distinctly that the level of acyl-CoA thioesterase is decreased or increased in a plant is produced by the method of Applicants' invention. Support for this amendment of claim 5 can be found in original claims 21 and 30, and in the specification, particularly on: page 2, lines 27-30; page 3, lines 1-5; page 5, lines 19-30; page 6, lines 1-30; and page 7, lines 1-4.

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Claims 10 and 11 have been amended to change claim dependency due to the previous cancellation of claim 9, which depended from claim 5. In their response dated January 21, 2004, Applicants' cancelled claim 9. As amended, claims 10 and 11 depend from claim 5.

Claims 21 and 30 have been further amended. To correct an inadvertent omission of a word in claim line 2, the preposition --in-- has been added immediately after "drives expression". This amendment is purely formal in nature and is fully supported by the original claims and specification. Also in these claims, part (b) has been deleted and part (e) has been amended due to the deletion of part (b). As amended, part (e) (now part (c) in amended claims 21 and 30) recites "the nucleotide sequence that is complementary to the nucleotide sequence of (a) or (b)."

New claims 37-39 have been added. The new claims depend from claim 5 and are fully supported by the original claims and specification. In particular, support for new claim 37 can be found in original claims 5, 21, and 30 and throughout the specification, particularly on page 11 at lines 10-12 and 18-20. Support for new claims 38 and 39 can be found in original claim 5 and in the specification, particularly on page 11 at lines 12-14, and on page 34, line 26 to page 35, line 7.

No new matter has been added by way of amendment of the claims or by the addition of the new claims.

Claims 5-8, 10-14, 17, 21-22, 24-30, and 37-39 are pending.

Reexamination and reconsideration of the application as amended are respectfully requested in view of the following remarks.

Claims 5-8, 10-14, 17, 21-22, and 24-30 Are Free of the Prior Art

Applicants respectfully acknowledge that the Examiner has determined that "[c]laims 5-8, 10-14, 17, 21-22, and 24-30 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method for producing beta-oxidation in a transformed plant using the isolated polypeptide of SEQ ID NO: 1." (Office Action mailed May 5, 2004, p. 6)

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The Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

Claims 1-3, 5-8, 10-14, 17, 21-22, and 24-30 have been rejected under 35 U.S.C. § 112, first paragraph. Claims 1-3 have been canceled. Claims 5, 21, and 30 have been amended. New claims 37-39 have been added. This rejection is respectfully traversed and should not be applied to the newly submitted claims.

*Written Description*

Claims 1-3, 5-8, 10-14, 17, 21-22, and 24-30 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of adequate written description. The Office Action asserts that the specification does not describe structural features common to or a representative number of the claimed genus of isolated polynucleotides that have 90% sequence identity to or comprise at least 200 contiguous nucleotides of SEQ ID NO: 1 encoding an acyl-CoA thioesterase. The Office Action indicates that this rejection of the claims is maintained for the reasons of record set forth in the Office Action mailed October 21, 2003.

As discussed in detail in Applicants' response dated January 21, 2004, claims 5, 21, and 30 recite both the functional and structural features of the claimed isolated nucleotide sequences, as *Regents of the University of California v. Eli Lilly and Co.*, 43 U.S.P.Q. 2d 1398 (Fed. Cir. 1997) requires. Claims 5, 21, and 30 recite that the fragment and variant nucleotide sequences encode polypeptides having acyl-CoA thioesterase activity or are the complements of such nucleotide sequences. The specification provides adequate description of the subject matter of the amended claims and its dependent claims so as to reasonably convey to one skilled in the relevant art that Applicants had possession of the invention as claimed. In particular, the specification discloses on pages 12-15 that the invention encompasses fragments and variants of the disclosed nucleotide sequence, wherein such fragments and variants encode polypeptides that retain acyl-CoA thioesterase activity. Accordingly, the subject matter of amended claims 5, 21, and 30 and their dependent claims is adequately described in the instant specification so as to

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reasonably convey to one of ordinary skill in the relevant art that, at the time of the invention, Applicants had possession of the claimed invention. The written description requirement of 35 U.S.C. §112, first paragraph, has been satisfied.

In the interest of furthering prosecution, however, Applicants have amended part (c) of claims 5, 21, and 30 to recite "a nucleotide sequence comprising at least 95% identity . . ." and have deleted part (d) of these claims. Part (d) had been directed to a nucleotide sequence comprising at least 200 contiguous bases of SEQ ID NO: 1 and encoding a polypeptide having acyl-CoA thioesterase activity.

In summary, in view of the amendments and above remarks, claims 5-8, 10-14, 17, 21-22, and 24-30 and the newly submitted claims satisfy the written description requirement of 35 U.S.C. §112, first paragraph, and the Examiner is respectfully requested to withdraw the rejection.

#### *Enablement*

Claims 1-3, 5-8, 10-14, 17, 21-22, and 24-30 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Office Action indicates that this rejection of the claims is maintained for the reasons of record set forth in the Office Action mailed October 21, 2003. The Office Action asserts that there is no guidance in the specification for determining which substitutions, additions, deletions, or recombinations of SEQ ID NO: 1 would retrieve a sequence that has 90% sequence identity or having at least 200 contiguous nucleotides in common with SEQ ID NO: 1 and still have acyl-CoA thioesterase activity. The Office Action concludes that the specification has not taught how to make nucleotide sequences having the activity encompassed by the present invention.

The Examiner is respectfully reminded that the Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation needed to practice the invention is not undue. *In re Wands* 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988). Furthermore, a considerable amount of experimentation is permissible, if it is

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merely routine, or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *Id.*

As discussed in detail in Applicants' response dated January 21, 2004, the specification provides sufficient guidance to make and identify the isolated nucleotide molecules encompassed by the claims. In particular, Applicants have provided the nucleotide sequence of SEQ ID NO: 1. The claimed nucleotide sequences vary from this sequence by structural parameters (*i.e.*, at least 90% identity to SEQ ID NO 1, or at least at least 200 contiguous bases of SEQ ID NO: 1) that can be determined by those of ordinary skill in the art. While methods for sequence alignments, sequence comparisons, and determining percent sequence identity are within the knowledge of one of ordinary skill in the art, additional guidance for is set forth in the specification on pages 19-24.

Moreover, the nucleotide sequences of the invention encode polypeptides having acyl-CoA thioesterase activity. Such nucleotide sequences include those that are fragments and variants of SEQ ID NO: 1 and that encode biologically functional acyl-CoA thioesterases. Methods for assaying whether the nucleotide sequences encode biologically functional acyl-CoA thioesterases are known in the art and are also provided in the instant specification on page 15 at lines 20-21. Accordingly, based on the guidance in the specification, one of ordinary skill in the art would be able to determine which nucleotide sequences are encompassed by the present invention.

Applicants again stress that when evaluating the quantity of experimentation required, the court looks to the amount of experimentation required to practice a single embodiment of the invention, rather than the amount required to practice every embodiment of the invention. *Id.* In the instant case, the quantity of experimentation required to practice the claimed invention amounts to two steps, identifying a nucleotide sequence that comprises at least 90% sequence identity to, or has at least 200 contiguous bases of, the nucleotide sequence of SEQ ID NO: 1, and then assaying the protein encoded thereby for functional activity. Thus, ample guidance is provided to allow one of skill in the art to identify additional nucleotide sequences encompassed by the claims 5, 21, and 30 and their respective dependent claims. Consequently, contrary to the

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conclusions of the Office Action, the quantity of experimentation necessary and the amount of guidance presented in the specification is sufficient to enable Applicants' claimed invention. Accordingly, Applicants submit that claims 5-8, 10-14, 17, 21-22, and 24-30 are enabled under 35 U.S.C. § 112, first paragraph.

As discussed above, Applicants have amended claims 5, 21, and 30 in the interest of furthering prosecution. Part (c) of these claims has been amended to recite "a nucleotide sequence comprising at least 95% identity . . ." and part (d) has been deleted.

In view of the amendments and above remarks, it is apparent that those of skill in the art would be able to practice Applicants' claimed invention without undue experimentation. Accordingly, the enablement rejection of claims 5-8, 10-14, 17, 21-22, and 24-30 should be withdrawn and not applied to the newly submitted claims.

The Rejection of the Claim 13 under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 3, 5-8, 10-14, 17, 21-22, and 24-30 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Claim 3 has been canceled. Claims 5, 21, and 30 have been amended. New claims 37-39 have been added. This rejection is respectfully traversed and should not be applied to the newly submitted claims.

The Office Action indicates that claim 3 is dependent on itself. This rejection of claim 3 is obviated by the cancellation of this claim.

The Office Action indicates that claim 5 indefinite for several reasons.

First, the Office Action indicates claim 5 recites a method of decreasing  $\beta$ -oxidation in a plant wherein the level the level of oil or at least one constituent of said oil is increased and asserts that the method of decreasing  $\beta$ -oxidation is unconnected to the increase in oil or at least one oil constituent. The Office Action further asserts that "the claim does not recite that the

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promoter/construct expresses the thioesterase[;] it merely recites that the promoter drives expression in a plant." (Office Action mailed May 5, 2004, p. 6).

Applicants respectfully disagree with this view of the Office Action for the following reasons. Claim 5 recites "a promoter *operably linked* to an acyl-CoA thioesterase nucleotide sequence" (emphasis added). The specification defines what Applicants intend by operably linked on page 27 at lines 4-6 as follows:

By "operably linked" is intended a functional linkage between a promoter and a second sequence, wherein the promoter sequence initiates and mediates transcription of the DNA sequence corresponding to the second sequence.

Thus, one of ordinary skill in the art in view of the instant specification would readily understand that the promoter of claim 5 *initiates and mediates transcription* of the acyl-CoA thioesterase nucleotide sequence. Accordingly, claim 5 is not indefinite for failing to recite that the promoter/construct expresses the thioesterase.

Second, the Office Action indicates that claim 5 does not recite a regeneration step. The Office Action indicates that the claim recites "transforming" a plant cell and asserts that because such "transforming" does not include contacting a plant with viral nucleic acids then a regeneration step is required in claim 5. The Office Action further asserts that "Applicant's viral method for plant transformation is not transformation but is properly called transduction since the nucleic acids are not incorporated into the cell's nucleus." (Office Action mailed May 5, 2004, p.4) (emphasis added)

In contrast to the view of the Office Action, the specification provides in the paragraph bridging pages 34-35:

A plant can also be transformed with an acyl-CoA thioesterase nucleotide construct or other nucleotide construct of the invention by contacting the plant with a virus or viral nucleic acids. Generally, such methods involve incorporating

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the nucleotide construct of interest within a viral DNA or RNA molecule. It is recognized that the an acyl-CoA thioesterase of the invention may be initially synthesized as part of a viral polyprotein which later may be processed by proteolysis in vivo or in vitro to produce the desired recombinant protein. Further, it is recognized that promoters of the invention also encompass promoters utilized for transcription by viral RNA polymerases. Methods for introducing nucleotide constructs into plants and expressing a protein encoded therein involving viral DNA or RNA molecules are known in the art. See, for example, U.S. Patent Nos. 5,889,191, 5,889,190, 5,866,785, 5,589,367 and 5,316,931; herein incorporated by reference.

Thus, in view of the instant specification, one of ordinary skill in the art would understand that claim 5 encompasses transforming at least one cell of a plant by viral methods that do not require a regeneration step. Accordingly, claim 5 is not indefinite for lacking a regeneration step.

Also in the section of the Office Action that concerns the alleged indefiniteness of claim 5 for lacking a regeneration step claim 5, Applicants were invited "to inspect page 5, lines 6-8 where regeneration is a required step for the 'preferred' methods of the invention." (Office Action mailed May 5, 2004, p. 5) Applicants respectfully remind the Examiner that the claims need not include the limitations of preferred embodiments of the invention. Should the Examiner disagree, Applicants respectfully invite the Examiner to specify the relevant section of Title 35 of the United States Code that sets forth the requirement that a claim must recite the limitations of a preferred embodiment of the invention.

In the interest of furthering prosecution, Applicants have amended claim 5 to clarify that their claimed method involves introducing a nucleotide construct into at least one cell of a plant. As is indicated on the specification on page 11 at lines 10-14, such "introducing" includes both stable transformation wherein the introduced nucleotide construct is stably integrates into the genome of the plant is capable of being inherited by progeny thereof and transient transformation

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wherein the introduced nucleotide construct does not stably integrate into the genome of the plant. In addition, Applicants have added new claims 37-39, which are directed to certain embodiments of their claimed method that are disclosed in the instant specification.

Third, the Office Action indicates that claim 5 is incomplete because it lacks an expression step. The Office Action asserts that there is no indication that the expression of an acyl-CoA thioesterase is related to a decrease in  $\beta$ -oxidation or an increase in oil or an oil constituent in the plant. While Applicants respectfully disagree with this position of the Office action in view of the discussion above, Applicants—in the interest of furthering prosecution and not to limit the scope of their claimed invention—have amended claim 5 to point out more distinctly that the level of acyl-CoA thioesterase is decreased or increased in the plant or at least one part thereof.

The Office Action indicates that claims 10 and 11 are indefinite because they depend from canceled claim 9. Applicants have amended claims 10 and 11 to depend from claim 5. As amended, these claims are not indefinite.

The Office Action indicates that claims 21 and 30 are indefinite for the omission of the preposition --in-- after the word "expression". To correct this inadvertent omission of a word in claim line 2, Applicants have added the preposition --in-- immediately after "expression". Accordingly, amended claims 21 and 30 are not indefinite.

In view of the amendments and remarks, it is submitted that the rejection under 35 U.S.C. § 112, second paragraph, should be withdrawn and not applied to the newly submitted claims.

The Rejection of the Claims Under 35 U.S.C. § 102(e) Should Be Withdrawn

Claims 1-3 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Allen *et al.* (U.S. Patent No. 6,677,502). Claims 1-3 have been cancelled. New claims 37-39 have been added. This rejection is obviated by the cancellation of claims 1-3 and should not be applied to the newly submitted claims.

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The Office Action indicates that U.S. Patent No. 6,677,502 discloses a polynucleotide sequence having 92.5% identity to SEQ ID NO: 1 encoding an amino acid having 100% identity to SEQ ID NO: 2 and that has acyl-CoA thioesterase activity. The Office Action further indicates that U.S. Patent No. 6,677,502 teaches expression cassettes comprising constitutive promoters.

The Office Action indicates that there is an attached sequence search report. Applicants did not receive the attached sequence search report with the Office Action. Applicants contacted the Examiner by telephone on May 9, 2004 and respectfully requested that he forward a copy of the sequence search report to Applicants undersigned representative. Applicants appreciate the time and courtesy of the Examiner in forwarding a copy of the sequence search report by facsimile on May 10, 2004. However, Applicants only received a copy of the search report that pertains to the amino acid sequence set forth in SEQ ID NO: 2. Applicants respectfully request that the Examiner forward with the next Office Action or Notice of Allowance a copy of the portion of the sequence search report that pertains to the nucleotide sequence set forth in SEQ ID NO: 1 of the instant application.

In view of the cancellation of claims 1-3, it is submitted that the rejection under 35 U.S.C. § 102(e), second paragraph, is obviated and should not be applied to the newly submitted claims.

### **CONCLUSION**

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. §§ 102 and 112 are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for not addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper.

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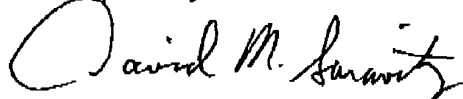
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However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



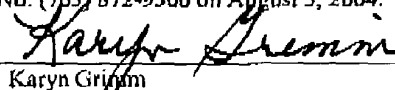
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## CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office at Fax No. (703) 872-9306 on August 5, 2004.

  
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